

**The University of North Carolina at Chapel Hill**  
**Consent for Storing Biological Samples Without Identifying Information**

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***DELETE THIS AND ALL OTHER INSTRUCTIONS IN ITALICS AND YELLOW HIGHLIGHTS.*** *The consent form must be written in 2<sup>nd</sup> person (e.g., You are being asked to take part in a research study about...)*

**IRB Study #** *(Leave blank if new submission.)*

**Consent Form Version Date:** *(Enter or update for all submissions.)*

**Title of Study:**

**Principal Investigator:**

**UNC-Chapel Hill Department:**

**UNC-Chapel Hill Phone number:**

**Email Address:** *Optional*

**Co-Investigators:** *Delete if not applicable*

**Faculty Advisor:** *Delete if not applicable*

**Funding Source and/or Sponsor:**

**Study Contact telephone number:**

**Study Contact email:**

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**What are some general things you should know about research?**

Research is designed to gain scientific information that may help other people in the future. You may not receive any direct benefit from participating. There also may be risks.

You may refuse to take part in research. If you are a patient with an illness, you do not have to be in research in order to receive treatment.

Details are discussed below. It is important that you understand this information so that you can make an informed choice. You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

**What is the purpose of this specimen repository or “biobank?”**

Research with blood, tissue or body fluids (specimens) can help researchers understand how the human body works. Research can also answer other questions by using specimens. Researchers may develop new tests to find diseases, or new ways to treat diseases. In the future, research may help to develop new products, such as drugs. Specimens are commonly used for genetic research. Sometimes researchers collect and store many specimens together and use them for different kinds of research, or share them with other scientists; this is called a specimen repository or “biobank.”

The purpose of this particular repository or biobank is to... *describe purpose for the specimen collection and storage and what you hope to learn from the stored samples.*

- *Inform subjects of the purpose of the repository.*
- *Inform subjects what specimens are to be collected and/or stored (i.e. blood, tissues, teeth etc).*
- *Provide a specific description of the research to be conducted with the specimens if known.*
- *Describe the types of genetic research that may be done in the future, e.g. "...looking for relationships between genes, the environment, and people's habits or diet, and different diseases." (May omit if there is certainty that genetic research will never occur, but this may be unlikely).*

#### **How will the specimens be collected?**

- *Provide specific details about how the specimen will be collected, OR*
- *if specimen already exists from previous clinical sources or research studies, inform subjects.*

#### **What will happen to the specimens?**

*Address specific areas about how the sample will be used and stored:*

- *Provide a clear description of the operation of the specimen repository*
  - *Where will the specimen be stored?*
  - *When will the specimens be destroyed?*
- *Inform subjects of conditions under which data and specimens will be released to other investigators.*

#### **What are Genome Wide Association Studies (GWAS)?**

*Delete if this does not apply to your study and you know data will never be submitted to GWAS*

The National Institutes of Health (NIH) has established a national database that will hold information from many individuals across the country, including medical information and genetic information. Your blood and tissues contain genes which are made of DNA that is unique to you. Access to this database will be controlled and limited to other researchers.

#### **What are the possible benefits to you?**

Benefits to you are unlikely. Studies that use specimens from this repository may provide additional information that will be helpful in understanding (specify if repository focus known).

#### **What are the possible risks or discomforts involved with the use of your specimens?**

*Describe immediate and long-term social, physical, and psychological risks/discomforts related to the specimen collection and storage. Address all risks that are applicable.*

- *Unknown risk: Subjects should be informed that there may be risks that at this time are unknown.*
- *Physical risks: If new samples are being collected include the physical risk associated with the sample collection for research purposes.*
- *Also include the following...*

Sometimes there are concerns, even if hypothetical, that people may find out things about you (for example, that your genes make you susceptible to a certain disease). These concerns are minimized with this repository, because the specimens will not be able to be linked to your identity, so it will be impossible for anyone to know which sample came from you.

**Will there be any cost to you for storage of the specimens?**

There will be no cost to you for the storage and use of the specimens for research purposes.

**Will you receive anything for the use of your specimens?**

Choose **ONE** applicable sentence. Describe payment or gift and schedule for their receipt. Address how payment will be prorated in the event the subject withdraws from the study prior to completion. Include information about any reimbursement for parking, transportation, etc. You will not receive anything for taking part in this research.

You will receive (specify) for taking part in this research.

**Who owns the specimens?**

Insert any contract, grant or agreement language related to specimen ownership or modify the following boilerplate.

Any blood, body fluids, or tissue specimens obtained for this purpose become the exclusive property of (specify organization that owns, e.g., the University of North Carolina at Chapel Hill, name of drug company or other sponsor, etc. Individual researchers do not own specimens, and should not be listed.). This organization may retain, preserve or dispose of these specimens and may use these specimens for research that may result in commercial applications. There are no plans to compensate you for any future commercial use of these specimens.

**How will your privacy be protected?**

The researchers will not have any identifying information about you so there is no risk to your privacy.

**Will you receive study results of future research involving your specimens?**

Most research with your specimens is not expected to yield new information that would be meaningful to share with you personally. In this case that would be impossible, because the researchers have no information that identifies you.

**Can you withdraw the specimen from this repository?**

You may not withdraw your specimen in the future because there are no identifiers on the specimen and the researchers will not know which specimen is yours.

**What will happen if you are injured by this research?**

**Omit this section if the specimens have already been collected.**

All research involves a chance that something bad might happen to you. This may include the risk of personal injury. In spite of all safety measures, you might develop a reaction or injury from having your specimen collected. If such problems occur, the researchers will help you get medical care, but any costs for the medical care will be billed to you and/or your insurance

company. The University of North Carolina at Chapel Hill has not set aside funds to pay you for any such reactions or injuries, or for the related medical care. However, by signing this form, you do not give up any of your legal rights.

**Who is sponsoring this research?**

This research is funded by *(name of Drug Company, the National Institutes of Health, etc.)*. This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

*When appropriate, the last sentence should be modified to disclose the nature of any potential conflicts of interest relating to this study, financial or otherwise.*

**What if you have questions about this research?**

You have the right to ask, and have answered, any questions you may have about this research. If you have questions, you should contact the researchers listed on the first page of this form.

**What if you have questions about your rights as a research subject?**

All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject you may contact, anonymously if you wish, the Institutional Review Board at 919-966-3113 or by e-mail to IRB\_subjects@unc.edu.

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*Keep signatures with body of form. If this section is on separate page include header with title of study and name of PI.*

**Subject's Agreement:**

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate. I agree to my specimen(s) being stored without the identifying code(s).

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Signature of Research Subject

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Date

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Printed Name of Research Subject

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Signature of Research Team Member Obtaining Consent

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Date

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Printed Name of Research Team Member Obtaining Consent